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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,179	06/20/2000	Maura Rooney	BSP2102US02	5883
22852	7590	08/09/2005	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			FOREMAN, JONATHAN M	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/597,179

Applicant(s)

ROONEY ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,25,28-30,32-39,57,58 and 60-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,25,28-30,32-39,57,58 and 60-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

New grounds of rejection are contained within this Office Action. Accordingly this action has been made Non-Final.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 38 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,833,631 to Nguyen.

In regards to claim 38, Nguyen discloses a guide wire (Figure 2) including an elongate core (102) composed of a nickel-titanium alloy (Col. 5, lines 6 – 8), a proximal portion and a distal portion; a continuous unitary coil (204) having a circular cross-section and being composed of a second material (Col. 3, lines 56 – 67; Col. 4, lines 45 – 48) and that surrounds a substantial portion of the length of the core and extending distal of the core (Col. 4, lines 36 – 44); and a polymeric tip (206) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a polymeric material (Col. 4, lines 6 – 16). When shrunk, the polymeric material extends at least partially within spaces between adjacent turns of the coil. The coil comprises a coating (Col. 4, lines 6 – 7).

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Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 22, 25, 28, 30, 33 - 35, 37, 38, 57, 58, 60, 63 - 65, 67, 68, 70 - 74, 76, 78, 79, 81 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,832,047 to Sepetka et al. in view of U.S. Patent No. 4,984,581 to Stice.

In regards to claims 22, 25, 28, 30, 33 - 35, 37, 38, 57, 58, 60, 63 - 65, 67, 68, 70 - 74, 76, 78, 79, 81 and 82, Sepetka et al. discloses a guide wire (Figure 1) including an elongate core (14) having a proximal portion (20) and a tapered distal portion (Col. 4, lines 26 - 27); a continuous unitary coil (16) having a circular cross-section and being composed of a second material (Col. 5, lines 58 - 63) and that surrounds a substantial portion of the length of the core and extending distal of the core (Figure 1); and a tip (40) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a material that extends within spaces between adjacent turns of the coil (Figure 1). The coil includes a pitch that varies at least once along the core (Figure 4). Sepetka et al. discloses the tip (40) as a solder or weld joint (Col. 5, line 68), but fails to disclose the tip comprising a polymeric material. Sepetka et al. also fails to disclose the core comprising a nickel-titanium alloy. Additionally, Sepetka et al. fails to disclose the coil surrounding the entire length of the core, being composed of stainless steel, having a rectangular cross-section or having a lubricious coating. However, Stice discloses a guidewire having a nickel-titanium alloy core (Col. 3, lines 42 - 51) and a polymeric tip which extending connects to the core by at least extending within spaces between

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adjacent turns of the coil (Col. 2, lines 64 – 68). Stice also discloses the coil being located only at the tip or extending the entire length of the core (Col. 2, lines 49 – 51), being composed of stainless steel (Col. 2, lines 51 – 55), having a rectangular cross-section (Col. 2, lines 44 – 49) and having a lubricous coating thereon (Col. 4, lines 6 – 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Sepetka et al. to include nickel-titanium as taught by Stice in order to allow the guide wire to deform under stress as it is moved through curved body channels, and recover to a strait configuration when the stress is removed (Col. 3, lines 56 – 62). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Sepetka et al. to include a lubricous coating thereon as taught by Stice (Col. 4, lines 6 – 10) in order to allow the guidewire to more easily travel through the patient's vasculature. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Sepetka et al. to include a rectangular cross-section as taught by Stice in that Stice discloses circular and rectangular cross-sections as being functionally equivalent (Col. 2, lines 44 – 49) and therefore interchangeable. Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tip as disclosed by Sepetka et al. to include a polymeric material as taught by Stice in that Stice discloses the polymeric material and solder as being functionally equivalent (Col. 3, lines 24 – 29) and therefore interchangeable.

5. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,832,047 to Sepetka et al. in view of U.S. Patent No. 4,984,581 to Stice as applied to claim 70 above, and further in view of U.S. Patent No. 5,947,940 to Beisel.

In regards to claim 75, Sepetka et al. in view of Stice fails to disclose using a precipitation hardened alloy as the coil material. Beisel discloses a precipitation hardened alloy as the coil

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material for aiding guide wire insertion into a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil of Sepetka et al. in view of Stice to include the precipitation hardened alloy as taught by Beisel to increase the coil stiffness and enhance torqueability. Furthermore, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

6. Claims 29 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,832,047 to Sepetka et al. in view of U.S. Patent No. 4,984,581 to Stice and further in view of U.S. Patent No. 5,947,940 to Beisel.

In regards to claims 29 and 61, Sepetka et al. discloses a guide wire (Figure 1) including an elongate core (14) having a proximal portion (20) and a tapered distal portion (Col. 4, lines 26 – 27); a continuous unitary coil (16) having a circular cross-section and being composed of a second material (Col. 5, lines 58 - 63) and that surrounds a substantial portion of the length of the core and extending distal of the core (Figure 1); and a tip (40) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a material that extends within spaces between adjacent turns of the coil (Figure 1). Sepetka et al. discloses the tip (40) as a solder or weld joint (Col. 5, line 68), but fails to disclose the tip comprising a polymeric material. Sepetka et al. also fails to disclose the core comprising a nickel-titanium alloy. Additionally, Sepetka et al. fails to disclose the coil being composed of a precipitation hardenable alloy. However, Stice discloses a guidewire having a nickel-titanium alloy core (Col. 3, lines 42 – 51) and a polymeric tip which extending connects to the core by at least extending within spaces between adjacent turns of the coil (Col. 2, lines 64 – 68). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Sepetka et al. to include nickel-titanium as

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taught by Stice in order to allow the guide wire to deform under stress as it is moved through curved body channels, and recover to a strait configuration when the stress is removed (Col. 3, lines 56 – 62). Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tip as disclosed by Sepetka et al. to include a polymeric material as taught by Stice in that Stice discloses the polymeric material and solder as being functionally equivalent (Col. 3, lines 24 – 29) and therefore interchangeable. Beisel discloses a precipitation hardened alloy as the coil material for aiding guide wire insertion into a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil of Sepetka et al. in view of Stice to include the precipitation hardened alloy as taught by Beisel to increase the coil stiffness and enhance torqueability. Furthermore, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

7. Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,832,047 to Sepetka et al. in view of U.S. Patent No. 4,984,581 to Stice as applied to claim 70 above, and further in view of U.S. Patent No. 5,885,227 to Finlayson.

8. In regards to claims 77, Sepetka et al. in view of Stice discloses a polymeric tip, but fails to disclose the tip including radio-opaque material. Finlayson discloses a guide wire having a polymeric tip (20) that includes radio-opaque material (Col. 3, lines 29 – 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric tip as disclosed by Sepetka et al. in view of Stice to include radio-opaque material as taught by Finlayson to allow the tip of the guide wire to be seen with an imaging device while performing a medical procedure.

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9. Claims 32 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,832,047 to Sepetka et al. in view of U.S. Patent No. 4,984,581 to Stice and further in view of U.S. Patent No. 5,885,227 to Finlayson.

10. In regards to claims 32 and 62, Sepetka et al. discloses a guide wire (Figure 1) including an elongate core (14) having a proximal portion (20) and a tapered distal portion (Col. 4, lines 26 – 27); a continuous unitary coil (16) having a circular cross-section and being composed of a second material (Col. 5, lines 58 - 63) and that surrounds a substantial portion of the length of the core and extending distal of the core (Figure 1); and a tip (40) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a material that extends within spaces between adjacent turns of the coil (Figure 1). Sepetka et al. discloses the tip (40) as a solder or weld joint (Col. 5, line 68), but fails to disclose the tip comprising a polymeric material including a radio-opaque material. Sepetka et al. also fails to disclose the core comprising a nickel-titanium alloy. However, Stice discloses a guidewire having a nickel-titanium alloy core (Col. 3, lines 42 – 51) and a polymeric tip which extending connects to the core by at least extending within spaces between adjacent turns of the coil (Col. 2, lines 64 – 68). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Sepetka et al. to include nickel-titanium as taught by Stice in order to allow the guide wire to deform under stress as it is moved through curved body channels, and recover to a strait configuration when the stress is removed (Col. 3, lines 56 – 62). Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tip as disclosed by Sepetka et al. to include a polymeric material as taught by Stice in that Stice discloses the polymeric material and solder as being functionally equivalent (Col. 3, lines 24 – 29) and therefore interchangeable.

Finlayson discloses a guide wire having a polymeric tip (20) that includes radio-opaque material (Col.

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3, lines 29 – 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric tip as disclosed by Sepetka et al. in view of Stice to include radio-opaque material as taught by Finlayson to allow the tip of the guide wire to be seen with an imaging device while performing a medical procedure.

11. Claims 36, 66, and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,832,047 to Sepetka et al. in view of U.S. Patent No. 4,984,581 to Stice as applied to claims 34, 64 and 78 above, and further in view of U.S. Patent No. 5,997,517 to Whitbourne.

12. In regards to claims 36, 66 and 80, Sepetka et al. in view of Stice discloses a polymeric coating, but fail to disclose the coating being colored. Whitbourne teaches the use of a colored coating with various medical devices such as guide wires to enhance the performance of the devices (Col. 4, lines 2 – 11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guide wire as disclosed by Sepetka et al. in view of Stice to include a colored coating as taught by Whitbourne to enhance the performance of the guide wire by assisting in the identification.

13. Claims 39, 69 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,832,047 to Sepetka et al. in view of U.S. Patent No. 4,984,581 to Stice as applied to claims 22, 57 and 70 above, and further in view of U.S. Patent No. 5,174,302 to Palmer.

In regards to claims 39, 69 and 83 above, Sepetka et al. in view of Stice disclose a unitary coil but fail to disclose the unitary coil comprising a multifilar wire. However, Palmer discloses a unitary coil comprising a multifilar wire (Col. 4, lines 17 – 27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Sepetka et al. in view of Stice to include a multifilar wire coil as taught by Palmer in order to create

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intermittent bands or regions of high radiopaqueness (Col. 4, lines 25 – 26) to aid in the visualization of the guidewire during a medical procedure.

14. Claims 84, 85 and 87 – 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,832,047 to Sepetka et al. in view of U.S. Patent No. 4,984,581 to Stice and further in view of U.S. Patent No. 4,932,419 to de Toledo.

In regards to claims 84, 85 and 87 - 89, Sepetka et al. discloses a guide wire (Figure 1) including an elongate core (14) having a proximal portion (20) and a tapered distal portion (Col. 4, lines 26 – 27); a continuous unitary coil (16) having a circular cross-section and being composed of a second material (Col. 5, lines 58 - 63) and that surrounds a substantial portion of the length of the core and extending distal of the core (Figure 1); and a tip (40) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a material that extends within spaces between adjacent turns of the coil (Figure 1). The coil includes a pitch that varies at least once along the core (Figure 4). Sepetka et al. discloses the tip (40) as a solder or weld joint (Col. 5, line 68), but fails to disclose the tip comprising a polymeric material. Sepetka et al. also fails to disclose the core comprising a nickel-titanium alloy. Additionally, Sepetka et al. fails to disclose the coil surrounding the entire length of the core, having a rectangular cross-section or having a lubricious coating or being a multifilar cross-wound coil. However, Stice discloses a guidewire having a nickel-titanium alloy core (Col. 3, lines 42 – 51) and a polymeric tip which extending connects to the core by at least extending within spaces between adjacent turns of the coil (Col. 2, lines 64 – 68). Stice also discloses the coil being located only at the tip or extending the entire length of the core (Col. 2, lines 49 – 51), having a rectangular cross-section (Col. 2, lines 44 – 49) and having a lubricous coating thereon (Col. 4, lines 6 – 10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Sepetka et al. to include nickel-

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titanium as taught by Stice in order to allow the guide wire to deform under stress as it is moved through curved body channels, and recover to a strait configuration when the stress is removed (Col. 3, lines 56 – 62). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Sepetka et al. to include a lubricous coating thereon as taught by Stice (Col. 4, lines 6 – 10) in order to allow the guidewire to more easily travel through the patient's vasculature. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Sepetka et al. to include a rectangular cross-section as taught by Stice in that Stice discloses circular and rectangular cross-sections as being functionally equivalent (Col. 2, lines 44 – 49) and therefor interchangeable.

Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tip as disclosed by Sepetka et al. to include a polymeric material as taught by Stice in that Stice discloses the polymeric material and solder as being functionally equivalent (Col. 3, lines 24 – 29) and therefore interchangeable. De Toledo discloses a guidewire having a multifilar cross-wound coil (Col. 3, lines 3 – 18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Sepetka et al. in view of Stice to be a multifilar cross-wound coil as taught by de Toledo to improve the torque response and steerability of the guidewire (Col. 3, lines 13 – 18).

15. Claim 86 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,832,047 to Sepetka et al. in view of U.S. Patent No. 4,984,581 to Stice and further in view of U.S. Patent No. 4,932,419 to de Toledo as applied to claim 84 above, and further in view of U.S. Patent No. 5,885,227 to Finlayson.

In regards to claim 86, Sepetka et al. in view of Stice and further in view of de Toledo discloses a polymeric tip, but fails to disclose the tip including radio-opaque material. Finlayson

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discloses a guide wire having a polymeric tip (20) that includes radio-opaque material (Col. 3, lines 29 – 35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric tip as disclosed by Sepetka et al. in view of Stice and further in view of de Toledo to include radio-opaque material as taught by Finlayson to allow the tip of the guide wire to be seen with an imaging device while performing a medical procedure.

Response to Arguments

16. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JMLF



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